United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

SUPPLEMENTAL PERMIT CONDITIONS

FOR FIELD TESTS OF PLANTS ENGINEERED TO PRODUCE PHARMACEUTICALS OR INDUSTRIAL PRODUCTS.

Permit: 04-040-01r, ProdiGene, corn

[Note: Any regulated article introduced not in compliance with the requirements of 7 CFR Part 340 or of any standard or supplemental permit conditions, shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of a plant pest, and the responsible party may be subject to fines or penalties as authorized by the Plant Protection Act.]

1. APHIS's Biotechnology Regulatory Services (BRS) and/or an APHIS PPQ Regional Biotechnologist or APHIS State Plant Health Director may conduct inspections of the test site, facilities and/or records at any time. APHIS may invite the FDA or State Regulatory Officials to participate in these inspections. Inspections will likely correspond to the beginning of the field test, mid-season or during flowering, at and/or following harvest, and during the post-harvest monitoring period. The permittee is required to notify the APHIS, BRS Permits office and the appropriate PPQ Regional Biotechnologist and State Regulatory Official(s):

- at least 7 calendar days before the anticipated planting date,
- at least 21 calendar days before the anticipated harvest/termination of the field test.

Provide APHIS with the contact information for each and every specific field test site, and indicate if planting and harvesting equipment will be moved between authorized field test sites (see also item 2 D below). **Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 F.R. 38561-63.**
Contact information for the APHIS PPQ Regional Biotechnologists is included on the attached map and for the State Regulatory officials, this information is maintained at
http://www.aphis.usda.gov/brs/It_sta.html.

2. The procedures, processes and safeguards which will be used to prevent escape, dissemination and persistence of the transgenic plant and its progeny at each of the intended destinations as described in the permit application, in APHIS-approved procedures and in these supplemental permit conditions must be strictly followed. The permittee must maintain records sufficient to verify compliance with these procedures, including information regarding who performed the activity. Persons performing such activities shall have received training as described in a training program submitted to and approved by APHIS. These records are subject to examination by APHIS. **APHIS, BRS must be notified of any proposed changes to the protocol referenced in the permit application.** In particular, please note the following conditions.

A. Applicants must ensure that any corn from previous seasons is harvested and removed in a radius of 0.25 mile of the transgenic corn plot, before the transgenic corn is sown. No corn can be grown within 1 mile (5,280 feet) of the field test site throughout the duration of any field test which involves open-pollinated corn. When pollen flow is controlled by placing bags around the corn tassels or by the use of male sterile plants and detasseling, there will be no other corn with 2,640 feet of the field test site, and the pharmaceutical corn must be planted no less than 28 days before or 28 days after any corn growing in a zone extending from 2,640 to 5,280 feet from the filed test site. When pollen flow is controlled by the use of male sterile plants and detasseling, detasseling must performed at least every 48 hours during the period of time of tassel emergence. Test plots will be monitored as stated in the permit application to ensure that plants are not

flowering. Test plots will be monitored for at least one year post-harvest.

B. To ensure that transgenic plants are not inadvertently commingled with plants to be used for food or feed, **a perimeter fallow zone of at least 50 ft. must be maintained** around the transgenic test site in which no crops are grown that will be harvested or used for food or feed. The perimeter fallow zone must start outside of any permitted border rows of non-transgenic plants that are the same as, or sexually-compatible with, the regulated article and it shall be managed in such a way as to allow detection and destruction of volunteer plants that are the same as or sexually compatible with the transgenic plants.

C. **Production of food and feed crops at the field test site and the perimeter fallow zone is restricted** during the growing season that follows harvest or termination of the field test**. Permission must be obtained from APHIS, BRS prior to planting any food or feed crop at the field test site and perimeter fallow zone during the post-harvest monitoring period specified in item 2A above.** Requests for such permission are not encouraged and will not be granted in cases where there is a reasonable potential for plant material derived from or originating from the regulated articles to become mixed with the proposed food or feed crop during harvesting.

D. To ensure that regulated articles are not inadvertently removed from the site, planting and harvesting equipment must be dedicated to use in the permitted test site(s) from the time of planting through the end of harvesting. After this time, APHIS authorization will not be required for this equipment to be used on APHIS-permitted sites planted to the same types of transgenic crops as authorized under this permit (e.g. the same or different sites planted to the same crop with the same target protein(s) in subsequent growing seasons under an extension of this permit or a different permit), but **authorization will be required from APHIS before this planting and harvesting equipment can be used on sites planted to crops not included under this permit. In the latter case, the permittee must notify APHIS/BRS and the PPQ Regional Biotechnologist and State Regulatory Official at least 21 calendar days in advance of cleaning this equipment for this purpose so that APHIS may schedule an inspection to ensure that the equipment has been cleaned appropriately.**

To minimize the risk of seed movement and commingling, equipment used for planting and harvesting, as well as other field equipment (*e.g.* tractors and tillage attachments, such as disks, plows, harrows and subsoilers) used at any time from the time of planting through the post-harvest monitoring period must be cleaned in accordance with procedures submitted to and approved by APHIS before they are moved off of the test site. Equipment used to off-load or transport harvested material must also be cleaned prior to loading and after transportation to the authorized site in accordance with procedures submitted to and approved by APHIS. Seed cleaning and drying must also be performed in accordance with the procedures submitted to and approved by APHIS so as to confine the plant material and minimize the risk of seed loss, spillage or commingling.

E. Dedicated facilities (locked or secured buildings, bins or areas, posted as restricted to authorized personnel only) must be used for storage of equipment and regulated articles for the duration of the field test. Before these facilities are returned to general use, they must be cleaned in accordance with procedures submitted to and approved by APHIS. In this case, **the permittee must notify APHIS, BRS, the PPQ Regional Biotechnologist and State Regulatory Official at least 21 calendar days in advance of cleaning facilities for return to general use so that APHIS may schedule an inspection to ensure that the facilities have been cleaned appropriately.**

Within **28** calendar days after planting, **submit a report** that includes the following information for **each field test site**:

A. A map of the site, with sufficient information to locate it, that includes:

- the GPS coordinates for each corner of the plot (inclusive of the border rows of any sexually compatible plants) and
- the location and the approximate number and/or acres of transgenic plants which were actually planted at the test site for each of the target proteins.

B. The total acreage of the test plot (exclude border rows, if any).

C. The distance from the genetically engineered plants to the **nearest** plants of the same crop which will be used for food, feed or seed production. A survey should be done within the distance specified in the chart below for any of these crop plants.

D. A list of the specific containment option(s) selected at **each** site if your permit allows different containment options (e.g. bagging flowers, border rows, or isolation distance).

Fax the report to the following APHIS personnel:

1. The Chief, Biotechnology Risk Assessment Staff at Area Code (301) 734 8669
2. The PPQ Regional Biotechnologist (fax number enclosed)
3. The State Regulatory Official (CBI-Deleted copy only)

Crop	**Scouting Distance**
Maize	One mile
Barley	One-eighth mile
Wheat	One-eighth mile
Rice	One-eighth mile
Tobacco	One-half mile

4. Consistent with standard permit conditions at 7 CFR 340.4(f) (9), **field test data reports must be submitted within 6 months after the end of the field test** (final harvest or crop destruct). **In addition, a post-harvest/post-season monitoring report must be submitted within 3 months after the end of the monitoring period** (designated under item 2.A. above) that includes the dates the field site and perimeter fallow zone were inspected for volunteers, the number of volunteers observed and the actions taken.

5. This Permit (APHIS form 2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food, feed, pharmacological, biologic or industrial use of regulated articles or their products (and co-mingled plant material). In the latter case, depending on the use, reviews by APHIS, the U.S. Food and Drug Administration or the U.S. Environmental Protection Agency may be necessary.

6. Consistent with standard permit conditions at 7 CFR 340.4(f) (10), APHIS shall be notified orally immediately upon discovery and in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article

For immediate oral notification, contact the following APHIS staff in the order indicated below.

1. APHIS BRS Deputy Administrator's office [phone number: (301) 734-7324]. Indicate that you wish to report an unauthorized or accidental release of a regulated article to the BRS Regulatory Division Director; or in that person's absence, to the Chief of either the BRS Biotechnology Permit Program Operations staff or the Biotechnology Risk Assessment staff, or the permit reviewer. In the event that one of these persons cannot be reached, contact:
2. The appropriate APHIS PPQ Regional Biotechnologist.
3. The appropriate APHIS State Plant Health Director.

Contact information is maintained at the APHIS Biotechnology Regulatory Services website at http://www.aphis.usda.gov/brs/regulatory.html

Unless otherwise directed, written notification should be sent to:

Animal and Plant Health Inspection Service (APHIS)
BRS Regulatory Division (2) Director, Rm. 5B54
4700 River Rd. Unit 147
Riverdale, MD 20737.

When the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application, or suffers an unusual occurrence (excessive mortality or morbidity or unanticipated effect on non-target organisms), APHIS shall be notified as soon as possible but no later than within 5 working days. In such cases, notice should be sent to:

Animal and Plant Health Inspection Service (APHIS)
Chief, Biotechnology Permit Program Operations, Rm. 5B53
4700 River Rd. Unit 147
Riverdale, MD 20737